

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and
THE PEOPLE OF THE STATE OF NEW
YORK, by LETITIA JAMES, Attorney
General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING
COMPANY, INC., a corporation;
QUINCY BIOSCIENCE, LLC, a limited
liability company; PREVAGEN, INC., a
corporation d/b/a/ SUGAR RIVER
SUPPLEMENTS; QUINCY BIOSCIENCE
MANUFACTURING, LLC, a limited
liability company; and MARK
UNDERWOOD, individually and as an
officer of QUINCY BIOSCIENCE
HOLDING COMPANY, INC., QUINCY
BIOSCIENCE, LLC, and PREVAGEN,
INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

[PROPOSED] ORDER

Plaintiff the New York Attorney General brought this action pursuant to New York General Business Law §§ 349 and 350 and New York Executive Law § 63(12). Following trial in this matter, the jury found by a preponderance of the evidence that the following claims were unsupported by competent and reliable scientific evidence and that they had the capacity or tendency to deceive:

- a. Prevagen improves memory;

- b. Prevagen is clinically shown to improve memory;
- c. Prevagen improves memory within 90 days;
- d. Prevagen is clinically shown to improve memory within 90 days;
- e. Prevagen reduces memory problems associated with aging;
- f. Prevagen is clinically shown to reduce memory problems associated with aging;
- g. Prevagen provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking; and
- h. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking.

Each of these advertising claims was therefore a violation of the New York Executive Law § 63(12), and the jury further found that claims (e) and (f) violate General Business Law §§ 349 and 350. Pursuant to Executive Law § 63(12), upon a finding of statutory fraud or a finding of illegality, this Court has broad remedial powers to grant equitable relief, including an injunction. New York General Business Law § 349 also provides for an injunction for violations of the General Business Law.

The Court hereby Orders:

1. Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC, along with their directors, officers, employees, representatives, agents, affiliates, subsidiaries, successors, and assigns (collectively, “Corporate Defendants”) are permanently enjoined from engaging in conduct in or affecting the State of New York or any New York consumer in violation of New York Executive Law § 63(12), New York General Business Law § 349, and New York General Business Law § 350.

Definitions

2. For the purposes of this Order, “advertising” includes any promotional or marketing materials of any type, including but not limited to television commercials or

infomercials, radio commercials or infomercials, websites, web ads, emails, books, pamphlets, in-store displays, direct mailers, product labeling or packaging, billboards, posters, social media posts, or other electronic, internet-based, or print media. For clarity, “advertising in the State of New York” includes any advertising viewable and/or accessible by consumers in the State of New York, whether or not such advertising is specifically targeted to New York consumers.

3. For purposes of this Order, “clearly and conspicuously” means that a required disclosure is easily noticeable (i.e., difficult to miss) and easily understandable by ordinary consumers, including in all of the following ways:

- a. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.
- b. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
- c. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
- d. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
- e. On a product label, the disclosure must be presented on the principal display

panel.

- f. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
- g. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
- h. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
- i. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, “ordinary consumers” includes members of that group.

4. For purposes of this Order, “competent and reliable scientific evidence” means tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. For claims that represent, directly or by implication, that a product can improve memory or provide other cognitive benefits or reduce or help decline in memory or cognition associated with aging, competent and reliable scientific evidence shall consist of at least one randomized, controlled, double-blind human clinical trial involving a dietary supplement product or a product containing the identical active ingredients fitting the parameters described in the first sentence of this paragraph. For clarity, the Madison Memory Study conducted from 2009 to 2011 does not satisfy this definition of “competent and reliable scientific evidence.”

5. For purposes of this Order, “dietary supplement product” means (1) any product labeled as a dietary supplement or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients for use by humans that is intended to be ingested and is not represented to be used as a conventional food.

Prohibited Representations

6. Corporate Defendants are permanently enjoined from representing in their advertising in the State of New York, expressly or by implication, that a dietary supplement product: (1) improves memory; (2) is clinically shown to improve memory; (3) improves memory within 90 days; (4) is clinically shown to improve memory within 90 days; (5) reduces memory problems associated with aging; (6) is clinically shown to reduces memory problems associated with aging; (7) provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking; or (8) is clinically shown to provide other cognitive benefits, including, but not limited to healthy brain function, a sharper mind, and clearer thinking (hereinafter the “Enjoined Claims”) until such time as there exists competent and reliable scientific evidence to support such claims as determined by the Court. To the extent that Corporate Defendants determine that they have developed competent and reliable scientific evidence sufficient to support an Enjoined Claim for a dietary supplement product, they may petition this Court, upon notice to the Office of the New York State Attorney General, for relief from this paragraph with respect to that Enjoined Claim.

7. Corporate Defendants are permanently enjoined, in their advertising in the State of New York, from using disclaimers in their advertising that contradict the principal message of such advertisements. Disclaimers that contain qualifying information that is necessary to prevent a claim from being deceptive shall be presented clearly and conspicuously, and shall be at least

as prominent as the claims to which they relate. Where possible, qualifying information that is necessary to prevent a principal claim from being deceptive should be incorporated into the principal claim.

8. Corporate Defendants are permanently enjoined, in their advertising in the State of New York, from relying on any endorsements or testimonials unless Corporate Defendants possess competent and reliable scientific evidence to support the claims made through such endorsements or testimonials.

9. It is further Ordered that Corporate Defendants, in connection with the labeling or advertising of any product, including but not limited to dietary supplement products and food products, are permanently restrained and enjoined from making, expressly or by implication, any representation in advertising in the State of New York about the health benefits, performance, or efficacy of any product, unless the representation is non-misleading and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the field to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

10. It is further Ordered that Corporate Defendants, in connection with the labeling or advertising of any product, including but not limited to dietary supplement products and food products, are permanently restrained and enjoined from making, expressly or by implication, any representation in advertising in the State of New York that the performance or benefits of any product are clinically proven or otherwise established, unless the representation is non-misleading and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards

generally accepted by experts in the field to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Reporting and Record-Keeping

11. With regard to any evidence upon which Corporate Defendants rely as substantiation for any claim covered by this Order, Corporate Defendants shall secure and preserve all underlying or supporting documents generally accepted by experts in the field as relevant to an assessment of the evidence, including:

- a. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of any test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- b. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- c. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- d. All documents referring or relating to any statistical analysis of any test data; and
- e. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

12. For any business of which any Corporate Defendant is a majority owner or controls directly or indirectly, Corporate Defendants must create and retain the following records

for 10 years after the entry of this order and retain each such record for 5 years:

- a. Accounting records showing the revenues from all products sold in New York State;
- b. Personnel records showing, for each person providing services to Corporate Defendants, whether as an employee or otherwise, that person's name, addresses, telephone numbers, job title or position, dates of service, and (if applicable) the reason for termination;
- c. Records of all New York consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any responses;
- d. All records necessary to demonstrate full compliance with this Order; and
- e. A copy of each unique advertisement, product label, or other marketing material making any representation covered by this Order.

13. It is further Ordered that, for the purpose of monitoring Corporate Defendants' compliance with this Order, Corporate Defendants must provide any of the above-identified documents within 14 days of receipt of a written request from the NYAG.

14. Beginning three months after the date of this Order and continuing for a period of three (3) years thereafter, Corporate Defendants shall submit to NYAG, no later than fifteen (15) days after the conclusion of each three-month period, quarterly reports describing with specificity their compliance with the provisions of this Order during the prior quarter. The reporting shall include:

- a. a summary of any current or anticipated advertising claims regarding dietary supplements made or anticipated to be made in advertising in the State of New York by Corporate Defendants during the reporting period;

- b. copies of all advertising that relates to dietary supplements disseminated in New York State during the quarter, including revisions to Corporate Defendants' websites (for the first report, Corporate Defendants must produce all advertising; for subsequent reports, they must produce any advertising that has changed since prior reports); and
- c. a summary of all evidence Corporate Defendants rely on in support of any current or anticipated advertising claims.

Retention of Jurisdiction

15. The Court shall retain jurisdiction over this matter for all purposes after entry of this Order.

SO ORDERED this ____ day of _____, 2024.

Hon. Louis L. Stanton
United States District Judge